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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,007	08/07/2006	Claude Mialhe	0518-1161	1299

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YOUNG & THOMPSON
209 Madison Street
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EXAMINER

OU, JING RUI

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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10/27/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/553,007	Applicant(s) MIALHE, CLAUDE	
	Examiner JING RUI OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/29/2010 and 02/26/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment filed on 01/29/2010 and the RCE filed on 02/26/2010. Claims 1 and 4-17 are pending. Claims 1 and 17 are independent. Claims 2 and 3 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/29/2010 has been entered.

Claim Objections

3. Claims 1 and 4-17 are objected to because of the following informalities:

- a) In the fifth paragraph of claim 1, the phrase "push the edge of at the rear end" is grammatically incorrect.
- b) In the six paragraph of claim 1, a phrase "configured to be" should be inserted before the limitations "maintained by the internal wall of the inner sheath."
- c) In the seventh paragraph of claim 1, the limitation "to slide" should be corrected to "to be slidable."
- d) In the 7 paragraph of claim 17, the phrase "upon contact with the segment" is grammatically incorrect.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 1 and 4-17 fails the 3-prong analysis set forth in the MPEP 2181 and will not be treated under 35 USC 112 sixth paragraph since the recitations "means for opening the nose" in claims 1 and 10 and "means for translation" in claims 1 and 17 are modified by sufficient structures for achieving the specified function.

5. Claim 13 is being treated under 35 USC 112 sixth paragraph, in which the "means of adjusting" requires a grip as supported by applicant's specification (Para. [0087]).

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 4-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In lines 2 and 5 of the fourth paragraph of claim 1, the limitation "the auto-expandable element" is being unclear as to refer to which of the first and second auto-expandable element.

b) In the fifth paragraph of claim 1, it is unclear on what component of the device that the inner sheath is mounted.

c) In the seventh paragraph of claim 1, the recitation "at the end furthest from the intermediate section" is being unclear at the end of what component.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindenberg et al (US Pat. No.: 5,433,723) in view of Garza et al (US Pat. No.: 4,665,918) and Martinez et al (US Pat. No.: 5,593,412).

In regard to Claims 1 and 17, Lindenberg et al discloses an implant delivery system, comprising: a vessel dilation device (Fig. 1) with an outer envelope (2); an implant (1), the implant includes an auto-expandable element (the distal end of the endoprosthesis 1, Col. 4, lines 25-29) which presses against the internal wall of the outer envelope (Fig. 1); the implant includes a second, hollow expandable element (the proximal end of the endoprosthesis 1) and a hollow intermediate section (the intermediate section of the endoprosthesis 1 is deformable by twisting since it is an expandable and bendable stent); a grip (5) that is an integral part of the outer envelope;

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a removable spacer (9), a plunger (3), a grip (12) that is an integral part of the plunger, and a central channel (Fig. 1) along the line of the outer envelope.

Lindenberg et al does not appear to disclose an inner sheath slidably disposed inside the outer envelop and outside the plunger, a grip that is an integral part of the inner sheath, and that the outer envelope has a tapered end piece and detailed structures of the end piece.

However, Garza et al teaches a stent delivery system comprising: an outer sheath 78) connected to a grip (86), an inner sheath (50) connected to a grip (64) and slidably disposed inside the outer sheath, a plunger (the portion 18 defined from 22 to 26) connected to a grip (30) and slidably disposed inside the inner sheath and a spacer between each grip (Figs. 1-13b). Furthermore, Martinez et al teaches an implant delivery system, comprising of an outer envelope (sheath, 18, Fig. 1) having a tapered end piece (distal end portion 32 is tapered, Fig. 1) at the distal end of the outer envelope and an implant have expandable portion (stent, Fig. 10) that is pressed against the sheath and is in contact with the internal wall of a nose, whereby the end piece consists of the nose (the tapered distal end portion 32 is nose, Fig. 1) and means for opening the nose, consisting of at least two longitudinal slots (weakened areas, 41-45, Fig. 2A) which divide the nose into several segments (sections, 51-55, Fig. 2A), nose segments are joined as required along the slots when the nose is closed (Fig. 2A, the nose segments are joint by connector as shown in Fig. 2A); temporary connector by slots between segments (Fig. 2A, the nose segments are joint by connector as shown in

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Fig. 2A); and the nose includes a central residual passage (central opening, 50, Fig. 2A).

Lindenberg et al, Garza et al, and Martinez et al are analogous art because they are from the same field of endeavor, implant delivery system.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Lindenberg et al, Garza et al, and Martinez et al before him or her, to modify sheath and plunger of the implant delivery system of Lindenberg et al to include an inner sheath connected to a grip and slidably disposed inside the outer sheath, that plunger to be connected to a grip and slidably disposed inside the inner sheath, and a spacer between each grip as taught by Garza et al and to modify the distal end of the outer envelope of Lindenberg et al to include a tapered end nose piece and detailed structures of the end nose piece as taught by Martinez et al.

The suggestion/motivation for modifying the sheath and plunger of the implant delivery system of Lindenberg et al to include an inner sheath connected to a grip and slidably disposed inside the outer sheath, that plunger to be connected to a grip and slidably disposed inside the inner sheath, and a spacer between each grip as taught by Garza et al would have been to provide an more convenient way of independently withdrawing each of the outer and inner sheaths and to permit selected distances to be maintained between each grip in the present of the spacers. The suggestion/motivation for modifying the distal end of the outer envelope of Lindenberg et al to include a tapered end nose piece and detailed structures of the end nose piece as taught by Martinez et al would have been to protect the implant from premature deployment and

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control the deployment of the implant. Until the delivery device reaches a target site, the distal end portion of the sheath is softened by exposing to a warm, physiologically compatible liquid and opened by the pushing force of the implant and the introducer, thereby to allow for retraction of the sheath and deployment of the implant (Martinez et al, Col. 3, lines 24-42). Applicant should have noted that the tapered end nose piece with slits is old and well-known in the art. For examples, both Johnson et al (US Pat No.: 6,596,011) and Fischell et al (US Pat. No.: 5,634,928) discloses an implant delivery device comprising a sheath having a taper end nose piece with slits. Furthermore, it is old and well-known that the nose includes a shape memory, which would facilitate the withdrawn of the delivery system from body or enable insertion of another implant without withdrawing the sheath out of the body. In addition, duplication of the essential working parts of a device such as the grips and the spacer involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8

Therefore, it would have been obvious to combine Garza et al and Martinez et al with Lindenberg et al to obtain the invention as specified in the instant claims.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 4-17 have been considered but are moot in view of the new ground(s) of rejection.

The recitation "deformable by twisting" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

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claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Johnson et al (US Pat No.: 6,596,011)

Fischell et al (US Pat. No.: 5,634,928)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING RUI OU whose telephone number is (571)270-5036. The examiner can normally be reached on 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, UYEN (JACKIE) HO can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. O./

Examiner, Art Unit 3773

10/21/2010

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773